



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/620,148 | 07/14/2003 | Yoshihiro Yoshihara | 382.1031CON | 2595 |
| 23280 | 7590 | 01/11/2006 | EXAMINER | |
| DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018 | | | HAMA, JOANNE | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1632 |

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/620,148 | YOSHIHARA, YOSHIHIRO |
| | Examiner Joanne Hama, Ph.D. | Art Unit 1632 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 October 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,6,7,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,6,7,11 and 12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Applicant filed a response to the Non-Final office Action of April 20, 2005 on October 24, 2005. Claims 1-3, 6, 11, 12 are amended. Claims 5, 8-10, 13-20 are cancelled.

Claims 1-4, 6, 7, 11, 12 are under consideration.

Priority

Examiner had indicated in the Office Action of April 20, 2005 that when the instant application was filed, it was not copending with the parent application (09/763,117). As such, Applicant cannot claim priority to the parent. It is acknowledged that Applicant has filed a Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR 1.137(b) and a Petition for a Three Month Extension of Time on October 19, 2005 for the parent application. However, at the time of writing this Office Action, neither Petition has been granted. Subsequently, the priority claims of the instant Application remain denied.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the parent case, 09/736,117, was not copending when the instant case was filed. As such, the instant application cannot be considered a continuation and cannot use the oath filed in 09/736,117.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 7, 11, 12 remain rejected in modified form under 35 U.S.C. 112,

first paragraph, because the specification, while being enabling for

a transgenic mouse comprising a nucleic acid sequence encoding a trans-synaptic tracer protein operably linked to a mammalian neuron specific promoter, wherein the trans-synaptic tracer protein is expressed in neurons of interest, does not reasonably provide enablement for a transgenic mouse comprising a nucleic acid sequence encoding a trans-synaptic tracer protein operably linked to a neuron specific promoter from any species of animal other than mammalian, wherein the trans-synaptic tracer protein is expressed in neurons of interest.

Applicant's arguments, see pages 4-6 of Applicant's response, filed October 24, 2005, with respect to the rejection of claims 1-4, 6, 7, 1, 12 have been fully considered and are persuasive in part.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record, April 20, 2005.

The Applicant points out that there are a number of promoters which are specific to particular neurons (Applicant's response, page 5). The list of promoters provided by the Applicant indicate that it was known at the time that there are a number of mammalian neuron-specific promoters that were known. However, no guidance was provided for the breadth of a neuron-specific promoter from any species of animal. The art at the time of filing teaches that promoters from other species of animals do not express transgenes similarly and require characterization. For example, Sashikant indicates in a Research Project Outline (copy provided for applicant; available at <http://research.case.psu.edu/projects/PEN04070.pdf>) that there are while there are similarities between the Hoxc8 regulatory regions, there are differences between mouse and fish regulatory regions of the Hoxc8 gene. Sashikant teach that one goal in generating transgenic mice comprising a transgene construct comprising a nucleic acid sequence encoding a reporter protein operably linked to a Hoxc8 promoter from either fish or mouse will provide insights on transcriptional machinery present in the mouse that can discriminate between two enhancers activities and how to relate to different axial levels of expression (Sashikant, page 4). As such, the neither the specification nor the art provide guidance to practice the claimed invention for its fullest breadth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 11, 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yoshihara PCT/JP99/04439, for reasons of record, April 20, 2005.

As the priority date has not been perfected, the rejection of claims 1-4, 6, 7, 11, 12 remain.

Claims 1-4, 6, 7, 11, 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yoshihara et al., 1999, Neuron, 22: 33-41, for reasons of record, April 20, 2005.

As the priority date has not been perfected the rejection of claims 1-4, 6, 7, 11, 12 remain.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 7, 11, 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshihara et al., 1999, Neuron, 22: 33-41, for reasons of record, April 20, 2005.

As the priority date has not been perfected, the rejection of claims 1-4, 6, 7, 11, 12 remain.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

Application/Control Number: 10/620,148
Art Unit: 1632

Page 8


DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER